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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,759	05/25/2001	Phyllis Shapiro	708-4057	4368

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,759	SHAPIRO, PHYLLIS	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-24* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☒ Claim(s) *1-3 and 5-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 12/9/03, are acknowledged. Amended claim 1, 9, and 14 are acknowledged.

Applicant's arguments, filed 12/9/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-3 and 5-24 are herein under examination.

Claim Objections

Claim 9 is objected to because of the following minor informality: There is a misplaced hyphen between the words "substitute" and "and" on line 3 that should be removed. Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 16-23 is maintained under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-23 are rejected due to the claim steps lacking correspondence to the preamble of these claims. In claim 16, the claim steps only contain correction factors multiplied by plasma or serum hemoglobin values when in actuality, the preamble states a method for correcting values in blood, plasma, or serum. Thus, it is unclear whether the preamble or the correcting step in this claim controls the metes and bounds of the claimed invention. Appropriate clarification of the metes and bounds of the claim via clearer claim wording is requested. Claim 23 is rejected due to a similar issue with the preamble in claim 15 from which it depends. Claims 17-22 are also rejected due to their direct or indirect dependency from claim 16.

Applicant argues alternative uses for the hemoglobin values but does not clarify the metes and bounds of the claims which is the basis for the rejection. Applicant states that plasma and serum are both components of whole blood and that the plasma fraction can be separated from the whole blood sample and analyzed separately. Applicant states that listing correction values for only plasma and serum in the claim reflects the fact that they are separate components of whole blood. Applicant concludes that the method steps are applicable to correcting interference in a blood chemistry value for blood, plasma, or serum. This is found unpersuasive as there does not appear to be any correcting of the blood value in the claim steps. The preamble mentions three values that may be corrected and the claim steps only address two values. Therefore, the metes and bounds of this claim is unclear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-15, 17-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chupp et al. (P/N 5,631,165) in view of Chang et al. (P/N 5,200,323) and Samsoondar (WO 98/39634).

Chupp et al. teach a system where information about the blood sample is entered into the controller of an automated system that activates the analyzers to perform analyses under the direction of the controller (col. 10, lines 54-67). Chupp et al. describe the system as including an analyzer module, a data station module, and a pneumatic unit (col. 11, lines 27-29). The data station module has "sufficient software algorithms to manipulate measured data, calculate parameters and display results in a variety of formats" (col. 11, lines 62-67). Chupp et al. further discuss the analyzer module in which sample tubes of blood are automatically transported with bar code labels that can be read with a bar code reader so that sample information can be inputted into the system controller (col. 25, lines 22-35). Chupp et al. teach correcting MCH and MCHC in blood by performing the mathematical computations described in b(1) – (2) of claim 9 where the constants to correct dimension units for formula 1 is 10 and for formula 2 is 100 (col. 53, lines 66-67 and col. 54, lines 1-26). Chupp et al. teach the use of setting hemoglobin flags if any results are abnormal or suspect (col. 61, lines 50-51) which suggests the blood sample tested may be normal or abnormal as stated in claim 3. Chupp et al. also describe anemic patients with increased reticulocyte counts as indicating rapid erythroid turnover suggesting acute blood loss or hemolysis (col. 1, lines 62-65) as stated in claims 5 and 6. However, Chupp et al. do not teach

the presence of an extracellular hemoglobin product or oxygen-carrying blood substitute such as recombinant human hemoglobin or the formulas being determined by cell-by-cell measurements.

Chang et al. describe the use of modified hemoglobin blood substitutes as alternatives to human donor blood, such as recombinant human hemoglobin (col. 3, lines 61-63). Chang et al. describe adding modified hemoglobin blood substitutes to a human plasma sample with a centrifugation step (abstract) which represents isolation and purification of animal blood, as stated in instant claims 8, 11, and 18.

Samsoondar describes a method of identifying and quantifying the concentration of a blood substitute (abstract). Samsoondar describes a method of taking the measured concentration of the blood substitute and correcting for its effect on a measured analyte concentration, such as serum/plasma total protein (abstract). Samsoondar describes determining the concentration of true hemoglobin in the presence of blood substitutes (abstract). Samsoondar describes using samples contained in labeled tubes in a blood analyzer (abstract). Samsoondar describes a user can specify a particular interferent to be analyzed (page 11, lines 2-4). Samsoondar describes screening samples by taking successive sample measurements for interferents and blood substitutes (page 11, second paragraph) which is reasonably interpreted as cell-by-cell measurements, as stated in instant claim 1.

Chupp et al. describe the presence of classes and subclasses of red blood cells (col. 3, lines 53-54) and how the two methods used can distinguish cells and subdivide the cell types into finer classifications (col. 3, lines 7-14). Chupp et al. also discuss the need for increasing the precision and accuracy of previous manual methods of hematology analysis by using automated systems (col. 7, lines 11-16). Chang et al. point out it would be highly desirable to screen human

blood and plasma to determine the safety of modified hemoglobin blood substitutes for humans (col. 4, lines 11-30). One of ordinary skill in the art would have been motivated to enhance the automated hematology analyzer and method for correcting MCH and MCHC values in blood, as stated by Chupp et al., by including all types of blood samples in use at the time of the invention such as those containing modified hemoglobin blood substitutes, as stated by Chang et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use samples including recombinant human hemoglobin and other modified hemoglobin blood substitutes (as stated by Chang et al. and Samsoondar) in automated methods and systems of obtaining accurate MCH and MCHC values (as stated by Chupp et al. and Samsoondar) including the successive cell-by-cell measurements as exemplified by Samsoondar, because this information would enhance understanding of safety and potential problems of the various types of blood and blood substitutes in humans at the time of the invention, as stated by Chang et al. (col. 4, lines 11-30). Thus, Chupp et al., in view of Chang et al. and Samsoondar, motivate the limitations in claims 1-3, 5-15, 17-22, and 24 of the instant invention.

Applicant notes that the Malin et al. reference (2002/0012904) is not available as prior art under 35 U.S.C. 103(c). This statement is acknowledged and another prior art reference (Samsoondar) has been used in the 35 U.S.C. 103(a) rejection. Applicant states that the Chupp et al. reference provides a type of analysis that cannot differentiate between red blood derived hemoglobin and exogenously derived hemoglobin. This is found unpersuasive as the Samsoondar reference in the 35 U.S.C. 103 (a) rejection clearly provides such an analysis. Applicant states one of skill in the art would not be motivated to look to Chupp et al. for methods

of measuring exogenous hemoglobin since Chupp et al. teaches only methods for measuring HGB within cells. This is found unpersuasive as the reasons for motivation to combine references can come from other factors mentioned in the prior art references which have been addressed above in the previous paragraph.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 24, 2004

ARDIN H. MARSCHEL
PRIMARY EXAMINER